

Serial No. 10/750,312

REMARKS

This is a response to the Office Action mailed October 4, 2006. Claims 1-15 and 18-26 are pending in the application. The Examiner is reminded that claims 2, 10, 12, 15, and 26 are withdrawn and still pending. Claims 1, 4-9, 11, 13, 14, and 19-25 have been rejected by the Examiner. Claims 2-3, 10, 12, 15, 18, and 26 are withdrawn from consideration.

Applicant requests that all previously withdrawn claims that depend from a rejected base claim be rejoined on the basis that they are patentable for at least the same reasons that their parent is patentable. These include claims 2, 3, 10, 12, and 15.

Claim Rejections 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 4-5, 9, 11, 13-14, 19, and 23-25 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 4,846,791 to Hattler et al. with U.S. Patent No. 6,364,903 to Tseng et al. cited to show inherency. Applicants respectfully disagree.

Hattler et al. teaches a catheter “to carry fluids into and out from the blood vessel of a patient ... having multiple fluid carrying passageways, or lumens.” (col. 1, lines 10-24, Hattler et al.). Specifically, Hattler et al. disclose “a multi-lumen catheter in which one end of an expandable tube is first introduced into a blood vessel” and then a “divider is subsequently inserted from the distal end of the tube and extends the length of the tube, thereby dividing the tube into a plurality of separate lumens.” (col. 2, lines 33-39, Hattler et al.) The separate lumens “allow a number of different medications to be administered to the patient at one time using the same catheter.” (col. 1, lines 22-24, Hattler et al.) A catheter tube 10 is disclosed in FIG. 1 with an outside surface that is free of holes or gaps that would be present if the tube 10 were formed of struts.

Serial No. 10/750,312

The Examiner states that Hattler et al. “explicitly fails to teach the stents includes struts.” The Examiner’s basis for inherency appears to be that “it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al.” The Examiner relies on a definition of a stent from a dictionary that defines a stent as “a slender thread, rod or catheter inserted into a tubular structure, such as a blood vessel.” Applicants respectfully disagree with Examiner’s assertion of inherency, since, as demonstrated below, the Examiner has not met the burden necessary to show inherency.

To anticipate a claim, a prior art reference must expressly or inherently teach each and every claim limitation. It is the patent office’s burden to show that a limitation is expressly or inherently disclosed. As correctly pointed out by the Examiner, Hattler et al. does not expressly disclose a tube, catheter, or stent with struts. On the contrary, Hattler et al. expressly discloses a catheter tube 10 in FIG. 1 with an outside surface that does not have struts, the tube having a surface that is free of holes or gaps that would be present if the tube 10 were formed of struts.

With respect to the requirement of inherency, MPEP 2112 V states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. ... Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. ... In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Thus, the Examiner must show that a catheter, tube, or stent with struts necessarily flows from the teachings of Hattler et al. Applicants demonstrate below that the Examiner has not

Serial No. 10/750,312

made this showing. The Examiner's apparent line of reasoning is as follows: since a stent is defined as a catheter and stents have struts, then the catheter in Hattler et al. has struts. The reasoning is deficient and circular. Note the term "stent" is not taught in Hattler et al., only "tube" and "catheter." Thus, even if all stents have struts (which they do not), the Examiner still has to show that the catheter or tube of Hattler et al. inherently is a stent with struts. The Examiner cannot.

As indicated above, Hattler et al. states that catheters are used to carry fluids in and out of blood vessels of patients. The definition of catheter in Meriam Webster Online Dictionary is consistent with Hattler et al.: "a tubular medical device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open." (www.meriamwebster.com) Catheters typically are not formed of struts, and thus, do not have openings or gaps in their surface so that the catheter can carry fluids.

Therefore, it is without question that the term "catheter" can include a catheter or tube without struts. Let us assume that the term "catheter" does include, in addition to a catheter without struts, a stent with struts, as the Examiner suggests. The Examiner's line of reasoning seems to suggest that the catheter of Hattler et al. must be a stent with struts. The Examiner has provided no evidence that the catheter disclosed by Hattler et al. necessarily must be a stent with struts. To show that a catheter disclosed by Hattler et al. necessarily must be a stent with struts, the Examiner must provide more support than "catheter tube includes struts since stents have struts as evidenced by Tseng et al," since catheters are known that do not have struts. The proposition that the catheter or tube of Hattler et al. can or might have struts, as exemplified by Tseng et al., is insufficient for establishing inherency, since such uncertainty is enough to negate an assertion of inherency.

Serial No. 10/750,312

The uncertainty of whether the catheter in Hattler et al. can be a stent with struts is removed by examining the teachings of Hattler et al. which negate the possibility of a catheter or tubular geometry with struts. The teachings of Hattler et al. require that the catheter tube be free of openings in the tube surface that are present in a tubular geometry including struts. As indicated above, the purpose of the multi-lumen catheter with multiple fluid carrying lumens is to carry different kinds of fluids separately into the blood vessel of a patient. The catheter tube must be free of openings not only to fulfill this specific function, but to generally to carry fluids into a patient. In support of this, Hattler et al. states that “as the divider is inserted into the tube, each of the outer edges or corners 32 of the divider contact the inside surface of the tube to form a fluid-tight seal extending the length of the divider between adjacent lumens (col. 4, lines 52-55, Hattler et al.). A tube, catheter, or stent with struts would not have a fluid-tight seal along the length of the divider. The tube of Hattler et al. must be free of openings present in a tubular geometry with struts, otherwise the tube would be unable to carry fluids (the intended purpose of the tube) since fluids would leak from the outside surface of the tube. Additionally, different fluids within the separate lumens would mix, defeating the purpose of the divider.

The Examiner also states that “Hattler teaches at column 4 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable.” Hattler et al. teaches “a relatively small radial expansion of the tube” (col. 5, lines 12-13). Although a tube composed of struts can facilitate radial expansion of the tube, a tube need not have such a geometry to radially expand. A tube of Hattler et al. without struts that is free of openings in the tube surface is quite capable of radial expansion in the manner described in Hattler et al. Hattler et al. points out that the “catheter tube is conventionally made of the flexible, expandable material such as amber latex, vinyl, or silicon rubber.” (col. 4, lines 20-22, Hattler et al.) Additionally, Hattler et al. describes

Serial No. 10/750,312

and shows in FIG. 7 expansion of the catheter: “the divider has cross-sectional dimensions slightly greater than the inside diameter of the catheter tube, thereby causing radial expansion of the tube as the divider is inserted, as shown in FIG. 7” (col. 4, lines 61-64, Hattler et al.).

In general, for inherency the Examiner must show that Hattler et al. discloses an embodiment of a catheter tube which necessarily has struts. Tseng et al. shows that a stent can have a tubular geometry composed of struts. The fact that a disclosed prior art apparatus can or might have a particular characteristic is insufficient for a showing that the apparatus inherently has such a characteristic. In the present case, Applicants have even shown that the catheter tube of Hattler et al. cannot have a tubular geometry composed of struts.

Thus, Hattler et al. do not expressly or inherently teach a stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts. In addition, Hattler et al. do not expressly or inherently teach a stent and a mandrel supporting the stent, the stent comprising a plurality of struts. Therefore, claims 1, 9, 19, 23, and 24 are allowable over Hattler et al. Claims 4 and 5 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable. Claims 11, 13, and 14 depend from claim 9 and are allowable for at least the same reason that claim 9 is allowable. Claim 25 depends from claim 24 and is allowable for at least the same reason that claim 24 is allowable. Please remove the anticipation rejection of claims 1, 4-5, 9, 11, 13-14, 19, and 23-25.

Claim Rejections 35 U.S.C. § 103(a)

Claims 1, 4-5, 9, 11, 13-14, 19, and 23-25

The Examiner has rejected claims 1, 4-5, 9, 11, 13-14, 19, and 23-25 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over Hattler

Serial No. 10/750,312

et al. with Tseng et al. to show inherency and, in any event, cited to show inherency. Applicants respectfully disagree.

The Examiner repeats the basis for inherency of a catheter or stent with struts stated above. Applicants have shown that the basis is insufficient for a showing of inherency. Additionally, Applicants have shown that Hattler et al. exclude the possibility of a catheter or stent with struts.

The Examiner states that “it would have been obvious to support any known stent or catheter tube including that disclosed by Tseng et al on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-62 for the obvious reasons to expect similar end results – a catheter assembly capable of being inserted into a blood vessel.”

The cited passages of Hattler et al. provide no motivation for modifying Hattler et al. so that a stent with struts is used with a divider. The “different configurations” at col. 5, lines 10-15 are different diameters of catheters, not surface tubular geometries. The diameter depends “upon the specific application and the diameter of the blood vessel involved.” (col. 5, lines 10-12). Although a tube composed of struts can facilitate radial expansion of the tube, a tube need not have such a geometry to radially expand. Additionally, “grooves 18 scored longitudinally” along the surface of the stent are specifically meant to facilitate radial expansion and do not suggest a tubular strut geometry.

Furthermore, it would not be obvious to support a catheter tube or stent with struts, including that disclosed by Tseng et al. on the divider of Hattler et al., since similar end results would not be expected. The multi-lumen catheter including the catheter tube and divider has an

Serial No. 10/750,312

end result beyond insertion into a blood vessel. The purpose of the multi-lumen catheter is to carry fluids into and out from the blood vessel of a patient, such that a number of different medications are administered to the patient at one time using the same catheter via separate lumens in the catheter. (col. 1, lines 11-24, Hattler et al.)

As discussed above, a divider within a tubular geometry with struts such as a stent with struts would not have a fluid-tight seal along the length of the divider, due to gaps or openings in the surface of the stent. Fluids within each of the separate lumens would leak from the outside surface of the tube and mix, defeating the purpose of the divider and the general purpose of the catheter, in general, which is to transport fluids. Since the proposed modification would render the multi-lumen catheter unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification, i.e., a multi-lumen catheter or stent with struts.

MPEP Section 2143.01 V

Since the Examiner has not made a prima facie case of obviousness with respect to claims 1, 9, 19, 23, and 24, these claims and claims dependent thereon are not obvious and are allowable. Please remove the obviousness rejections.

Claims 6-8 and 20-22

The Examiner has rejected Claims 6-8 and 20-22 under 35 U.S.C. § 103 (a) as being unpatentable over Hattler et al in view of Tseng et al. Applicants respectfully disagree.

As shown above, claim 1 is allowable over Hattler et al. in view of Tseng et al. Claims 6-8 depend from claim 1 and allowable for at least the same reason that claim 1 is allowable.

Claims 20 recites “stent and a mandrel supporting the stent, the stent comprising a plurality of struts.” Applicants have shown that Hattler et al. does not teach or suggest the above claim limitation. For the reasons described above, claim 20 is not unpatentable over Hattler et al

Serial No. 10/750,312

in view of Tseng et al. Claims 21 and 22 depend from claim 20 and are allowable for at least the same reason that claim 20 is allowable.

Serial No. 10/750,312

CONCLUSION

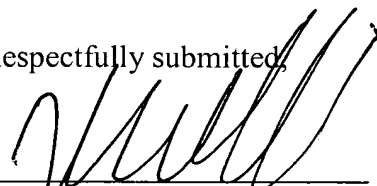
Claims 1-15 and 18-26 are pending in this application. Applicant respectfully submits that rejected claims 1, 4-9, 11, 13, 14, 19, and 23-25 are in condition for allowance. Applicants respectfully request the Examiner to enter the foregoing amendments and pass the case to issue.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0297.

Date: January 4, 2007

Squire, Sanders & Dempsey LLP
One Maritime Plaza, Suite 300
San Francisco, CA 94111-3492
Telephone: 415.954.0297

Respectfully submitted,



Mark Lupkowski, Ph.D.
Reg. No. 49,010
Attorney for Applicant